DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

January 17, 1998

Our Reference Numbers: 96-1403 and 97-0770

Dr. Rimmert J. Wolters
Organon Teknika B.V.
Boseind 15
Boxtel, Netherlands 5281 RM

Dear Dr. Wolters:

Enclosed is a product license which authorizes, Organon Teknika B.V., U. S. License No. 1103, to manufacture and sell (For Further Manufacturing Use) Human T-Lymphotropic Virus Type I Antigen (I. e., HTLV-I p21E Antigen). This HTLV-I p21E Antigen is to be used in a shared manufacturing arrangement with Organon Teknika Corporation (U.S. Lic. # 956), Durham, North Carolina, U.S.A., for incorporation into Vironostika[R] HTLV-I/II Microelisa System.

The lot release provisions contained in Title 21, Code of Federal Regulations, Section 610.2 will not be applied to HTLV-I p21E Antigen (For Further Manufacturing Use) at this time. However, the results of all required testing should accompany each lot of HTLV-I p21E Antigen (For Further Manufacturing Use) for inclusion in the Vironostika [R] HTLV-I/II Microelisa System release protocol submitted to the Center for Biologics Evaluation and Research (CBER) by Organon Teknika Corporation. Lot surveillance and sample testing on the HTLV-I p21E Antigen (For Further Manufacturing Use) may be instituted at any time should such action be deemed necessary by the Director of CBER.

Any lot of HTLV-I p21E Antigen (For Further Manufacturing Use) found to fall outside of the approved specifications, including expiration dating periods, should be withdrawn from the market. In addition, any reports of significant product defects or product complaints concerning the use of the HTLV-I rp21E Antigen (For Further manufacturing Use) should be submitted to the Office of Compliance, CBER, HFM-650.

The dating period for this product is 24 months when stored at -70C°. Any request to extend this dating period must be accompanied by the results of ongoing stability studies.

In addition, your request to supplement your establishment license application to include areas for the manufacture of HTLV-I p21E Antigen (For Further Manufacturing Use), Reference Number 97-0770, has been approved. The information contained in this supplement will be included in your establishment license application file.

If you wish to prepare the licensed product other than as specified in your approved license applications, it may be necessary for you to submit a supplement to either your product or establishment license application for review and approval prior to implementation.

Please acknowledge receipt of the enclosed product license by writing to the Director, Division of Blood Applications (HFM-370), Food and Drug Administration, CBER, c/o Document Control Center (HFM-99), Woodmont Office Center, Suite 200N, 1401 Rockville Pike, Rockville, Maryland 20852-1448.

Sincerely yours,

Jay S. Epstein, M.D.
Director
Office of Blood Research
and Review
Center for Biologics
Evaluation and Research

Jerome A. Donlon, M.D., Ph.D.
Director
Office of Establishment Licensing
and Product Surveillance
Center for Biologics
Evaluation and Research

Enclosures